UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/919,932 | 08/02/2001 | Bettina Moeckel | 211707US0X | 4629 |

22850 7590 07/15/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

| EXAMINER | |
|---|---|
| HUTSON, RICHARD G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | 15 |

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/919,932 | MOECKEL ET AL. | |
| | Examiner | Art Unit | |
| | Richard G Hutson | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *8-20 and 22-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10,14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

Claims 1-40 are at issue and are present for examination.

### *Election/Restrictions*

Applicant's election with traverse of Group I, drawn to an isolated polynucleotide which encodes a protein (SEQ ID NO: 2), Claims 1-7 and 21, in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the office has not provided adequate reasons and/or examples to support a conclusion of patentable distinctness between the identified groups. With respect t the previous restriction of Groups I, II and IV as "structurally unrelated", applicants submit that the office has merely made conclusory statements and has not provided evidence to suggest that these groups are "structurally unrelated" as alleged.

Applicants note that the M.P.E.P. describes unrelated inventions as, for example, "an article of apparel such as a shoe, and a locomotive bearing," or "a process of painting a house (and) of a process of boring a well". While applicants submitted examples from M.P.E.P. 806.04 are acknowledged,

M.P.E.P. 806.04 states that "two different combinations, not disclosed as capable of use together, having different modes of operation, different functions, or different effects are independent" (MPEP § 806.04, MPEP § 808.01).

As was previously stated, Inventions I, II and IV are structurally unrelated, thus the inventions are unrelated. Inventions are unrelated if it can be shown

that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Groups I and the *Coryneform glutamicum* strain of Group II each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotides of Group I are comprised of a nucleic acid sequence and capable of use as a hybridization probe. The animal feed stuff of Group IV are comprised of L-methionine and capable of use as an animal feedstuff. The *Coryneform glutamicum* strain of Group II is a living cell comprising polynucleotides, proteins, carbohydrates and lipids and capable of use in producing amino acids. Thus as each of the groups are independent as defined above based upon their different illustrated functions. Each of the groups are also as discussed above. Thus since each of the groups I, II and IV are independent and distinct they are unrelated as defined above (MPEP § 806.04).

Applicants further argue that based on the classification of the inventions of groups I and II in the same class and subclass, they cannot reasonably be deemed as directed to *completely* different technical fields as discussed above. While it is admitted that the different inventions of Groups I and II are not to "*completely* different technical fields", they are unrelated as discussed above and thus restriction is proper.

Applicants traverse the restriction between Group II drawn to a *Corynebacterium glutamicum* strain and Group III drawn to a method of producing an L- amino acid, which were previously characterized as being

related as product and processes of use, on the basis that there is no evidence of record that the claimed bacteria can be "used to synthesize and characterize a nucleic acid" nor has the office shown that the proposed use "to synthesize and characterize (a) nucleic acid" is materially different from what is claimed. This argument is not found persuasive on the basis that clearly the claimed *Corynebacterium glutamicum* strain can be used to synthesize a nucleic acid, and as the office has not presented evidence of such, applicants have also not presented evidence that such a use is not possible. With respect to applicants assertion that the office has not shown that the proposed use "to synthesize and characterize (a) nucleic acid" is materially different from what is claimed, this fact appears evident however if it is applicants intent to suggest otherwise, this should be taken into account in the ultimate consideration of the claims of Group III. Thus as was previously stated, the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

Applicants traverse the restriction between Group I drawn to a polynucleotide and Group III drawn to a method of producing an L- amino acid, which were previously characterized as being unrelated on the basis that the invention of Group I is neither used nor made by the method of Group III, on the basis that the office has provided no reasoning to support this assertion and that as discussed above M.P.E.P. 806.04 teaches that unrelated inventions are directed to "*completely* different technical fields." This argument is not found persuasive on the basis that as previously stated the polynucleotides of Group I are clearly not made or used by the claimed method of Group III and as

discussed above, while it is admitted that the different inventions of Groups I and III are not to "*completely* different technical fields", they are unrelated as discussed above and thus restriction is proper.

Applicants traverse the restriction between Group IV an animal feedstuff and Group III drawn to a method of producing an L- amino acid, which were previously characterized as being related as processes of making and product made, on the basis that there is no evidence of record that the claimed product can be "made synthetically (chemically)" or that a "synthetic" process would be materially different from the claimed process. This argument is not found persuasive on the basis that clearly the claimed animal feedstuff can be made synthetically by process that are outside the scope of the claimed process and, applicants have also not presented evidence that such method of making is not possible. With respect to applicants assertion that the office has not shown that a proposed synthetic process" would be materially different from the claimed process, this fact appears evident, however if it is applicants intent to suggest otherwise, this should be taken into account in the ultimate consideration of the claims of Group III. Thus as was previously stated, the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

Applicants traverse the restriction between Group I drawn to a *polynucleotide* and Group V drawn to a method of obtaining a cDNA or RNA, which were previously characterized as being related as product and processes of use, as above traversal of Group I and Group III, on the basis that there is no evidence of record that the claimed polynucleotide can be "used to synthesize

the encoded proteins". As stated above this proposed use of the claimed polynucleotide is obvious and as above applicants have presented no evidence to suggest otherwise.

As above, Applicants traverse the restriction between Groups II and IV and the invention of Group V, which were previously characterized as being unrelated on the basis that the invention of Groups I and IVI are neither used nor made by the method of Group V, on the basis that the office has provided no reasoning to support this assertion and that as discussed above M.P.E.P. 806.04 teaches that unrelated inventions are directed to "*completely* different technical fields." This argument is not found persuasive on the basis that as previously stated the inventions of Groups II and IV are clearly not made or used by the claimed method of Group V and as discussed above, while it is admitted that the different inventions of Groups II and IV and the invention of Group V are not to "*completely* different technical fields", they are unrelated as discussed above and thus restriction is proper.

Applicants further traverse the restriction of Groups III and V as independent as they comprise different steps, utilize different products and produce different results, on the basis that the term "independent" means that there is no disclosed relationship between the two or more subjects disclosed and applicants note that both inventions are classified in the same class, (i.e. 435). This argument is not found persuasive and each of the inventions of Groups III and V which are to drawn to different methods of production of an L-amino acid (Group III, 435/106) and methods of obtaining a cDNA or RNA

(Group V 435/6) are clearly independent and patentably distinct as can be seen in the different classifications of the claimed methods, 435/106 versus 435/6.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-20 and 22-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 13.

***Priority***

Applicants claim of priority to US Provisional Application No. 60/294,252, filed 5/31/2001 and German Application Nos. DE10043334.0, filed 9/2/2000, and DE 10109690.9, filed 2/28/2001, is acknowledged.

***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosures, Paper No. 9, filed 12/5/2001, Paper No. 10, filed 2/11/2002, Paper No. 11, filed 9/5/2002 and Paper No. 14, filed 6/13/2003, is acknowledged. Those present and considered have been initialed.

***Specification***

The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): 37 CFR 1.821. (d) states "Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. On page 25 of specification, applicants specification contains a table which comprises a number of nucleic acid sequences for which there does not appear to be an associated SEQ ID NO.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Appropriate correction is required.

***Claim Objections***

Claims 1, 5 and 7 are objected to because of the following informalities:

Claims 1 and 7 each recite "which **codes** for ". This should be "which **encodes** for".

It is suggested that applicants place a "colon" after "consisting of" and "comprising" in claims 1 and 5, respectively.

Claim 21 recites "a vector which **carries** a polynucleotide". It is suggested that this be amended to "a vector which **comprises** a polynucleotide"

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (claims 2-7 and 21 dependent on) is indefinite in that it is unclear in the recitation "metY gene of coryneform bacteria". What is and what is encompassed by the "metY gene of coryneform bacteria"? While applicants teach on page 2-3 of the specification that the invention provides a polynucleotide which codes for the metY gene ... and corresponding polypeptides having the enzymatic activity of o-acetylhomoserine sulhydrylase, it remains unclear if a necessary limitation of the metY gene is that it encodes a polypeptide with o-acetylhomoserine sulhydrylase enzymatic activity.

Claim 1 c) is indefinite in that it is drawn to the polynucleotide which is complementary to the polynucleotides of a) or b). Since all of the polynucleotides

of a), b), c) and d) must "code" for the metY gene, part c) is confusing in that it is unclear how if the polynucleotides of a) and b) "code" for the metY gene how can the complement (i.e. the opposite strand) of a) and b) also encode for the metY gene?

Claim 5 recites the limitation "The DNA" of claim 2. There is insufficient antecedent basis for this limitation in the claim 2, as claim 2 is drawn to "The polynucleotide".

Claim 5 is indefinite in the parts (ii) and (iv), in that it is unclear how parts (ii) and (iv) are different. Part (ii) is drawn to those sequences which correspond to sequence (i) (i.e. SEQ ID No. 1) within the range of the degeneration of the genetic code, and hence part ii) is interpreted as limiting the claimed DNA such that it must encode the same amino acid sequence as SEQ ID NO: 1 (i.e. SEQ ID NO: 2). Part iv) is drawn to a sense mutation of (i) (i.e. SEQ ID NO: 1) which is interpreted as a DNA sequence which must encode the same amino acid sequence as SEQ ID NO: 1 (i.e. SEQ ID NO: 2). Thus the two different parts of claim 5 are confusing in that they are interpreted as meaning the same thing.

Claims 5 and 6 are indefinite in the recitation of "hybridizes" as this term is unclear absent a statement of the conditions under which the hybridization reaction is performed. Nucleic acids which will hybridize under some hybridization conditions will not necessarily hybridize under different conditions. As such it is unclear how homologous to the sequence of SEQ ID NO:1, a sequence must be to be included within the scope of these claims. While claim 6 further limits the conditions of claim 5 part (iii) such that the hybridization occurs

at a stringency corresponding to at most 2X SSC, applicants reference to "a stringency corresponding to at most 2X SSC" is unclear. Is it applicants intent that the claimed hybridization solution contains at most 2X SSC (i.e. less then 2X SSC) or is applicants intent that the stringency corresponds to at most 2X SSC (i.e. less then conditions of stringency of 2X SSC, which would correspond to salt conditions of greater then 2X SSC).

Further it is unclear in applicants have not indicated any temperature for the hybridization, and thus the claim remains indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 5, 6 and 21 are directed to all possible polynucleotides which are at least 70% identical to a polynucleotide which encodes the amino acid sequence of SEQ ID NO: 2 or all possible polynucleotides which comprise a mere 15 successive nucleotides of a polynucleotides which is at least 70% identical to a polynucleotide which encodes the amino acid sequence of SEQ ID NO: 2 and host cells comprising said polynucleotide (claims 1 and 21) wherein

said polynucleotide is capable of replication in coryneform bacteria (claim 2) or is a RNA (claim 3) or those DNAs which hybridize with the nucleotide sequence of SEQ ID NO: 1 (claims 5 and 6). The specification, however, only provides a single representative species of polynucleotide (i.e. SEQ ID NO: 1) encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these enzymes by any identifying structural characteristics or properties. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-3, 5, 6 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide which encodes a protein having the amino acid sequence of SEQ ID NO: 2, wherein said protein has o-acetylhomoserine sulhydrylase activity, does not reasonably provide enablement for any polynucleotide which comprises a mere 15 successive nucleotides of a polynucleotide which is a mere 70% identical to a polynucleotide which encodes the amino acid sequence of SEQ ID NO: 2. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-3, 5, 6 and 21 are so broad as to encompass any polynucleotide which are at least 70% identical to a polynucleotide which encodes the amino acid sequence of SEQ ID NO: 2 or any polynucleotides which comprises a mere 15 successive nucleotides of a polynucleotides which is at least 70% identical to a polynucleotide which encodes the amino acid sequence of SEQ ID NO: 2 and host cells comprising said polynucleotide (claims 1 and 21), wherein said polynucleotide is capable of replication in coryneform bacteria (claim 2) or is a RNA (claim 3) or those DNAs which hybridize with the nucleotide sequence of SEQ ID NO: 1 (claims 5 and 6).

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. The claims rejected under this section of U.S.C. 112, first paragraph, place insufficient structural and

unclear if any functional limits on the claimed polynucleotides. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The same is true of a polynucleotide sequence, as the nucleic acid sequence of the polynucleotide directly correlates with the amino acid sequence of the polypeptide. However, in this case the disclosure is limited to a polynucleotide which encodes a protein having the amino acid sequence of SEQ ID NO: 2.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a polynucleotides sequence where nucleic acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any polynucleotide and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given polynucleotide to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass those polynucleotides having the claimed structural relationship to

SEQ ID NO: 1, because the specification does not establish: (A) regions of the polynucleotide structure which may be modified without effecting the desired activity; (B) the general tolerance of the claimed polynucleotides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleic acid residue of SEQ ID NO: 1 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those polynucleotides of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polynucleotide with the claimed structural relationship to SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is

unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Hwang et al. (Database EMBL, Accession No. AF220150, 2/5/2001).

Hwang et al. teach the *Corynebacterium glutamicum* O-acetylhomoserine sulfhydrylase gene which comprises a polynucleotide sequence that has a best local similarity score of 99.9 % between nucleotide 8 and nucleotide 1677 of SEQ ID NO: 1 and encodes at least15 successive nucleotides of a polynucleotide which is at least 70% identical to a polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2. Thus claims 1, 2, 5 and 6 are anticipated by Hwang et al.

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al. (Database EMBL, Accession No. AF052652, March 1998, See IDS, Paper No. 10, ref AP).

Park et al. teach the *Corynebacterium glutamicum* homoserine O-acetyltransferase gene which comprises a polynucleotide sequence that has a best local similarity score of 99.5 % between nucleotide 1285 and nucleotide 1720 of SEQ ID NO: 1 and encodes at least15 successive nucleotides of a polynucleotide which is at least 70% identical to a polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2. Park et al. Thus claims 1, 2, 5 and 6 are anticipated by Park et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hwang et al. (Database EMBL, Accession No. AF220150, 2/5/2001) or Park et al. (Database EMBL, Accession No. AF052652, March 1998, See IDS, Paper No. 10, ref AP).

As discussed above, Hwang et al. teach the *Corynebacterium glutamicum* O-acetylhomoserine sulfhydrylase gene which comprises a polynucleotide

sequence that has a best local similarity score of 99.9 % between nucleotide 8 and nucleotide 1677 of SEQ ID NO: 1 and encodes at least 15 successive nucleotides of a polynucleotide which is at least 70% identical to a polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2.

Also discussed above, Park et al. teach the *Corynebacterium glutamicum* homoserine O-acetyltransferase gene which comprises a polynucleotide sequence that has a best local similarity score of 99.5 % between nucleotide 1285 and nucleotide 1720 of SEQ ID NO: 1 and encodes at least15 successive nucleotides of a polynucleotide which is at least 70% identical to a polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2. Park et al.

One of ordinary skill in the art at the time of filing would have been motivated to express either of the polynucleotides taught by Hwang et al. or Park et al. as an RNA, so that the encoded proteins could be produced, in order to study the mechanism of actions of each of the identified enzymes involved in methionine biosynthesis in *Corynebacterium glutamicum*. As a necessary step in the production of the encoded protein, a mRNA copy of the taught polynucleotides is first generated. The reasonable expectation of success comes from the high degree of knowledge in the art of heterologous in vitro protein expression as supported by the number of commercially available in vitro transcription/translation kits.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hwang et al. (Database EMBL, Accession No. AF220150, 2/5/2001) or Park et

al. (Database EMBL, Accession No. AF052652, March 1998, See IDS, Paper No. 10, ref AP).

As discussed above, Hwang et al. teach the *Corynebacterium glutamicum* O-acetylhomoserine sulfhydrylase gene which comprises a polynucleotide sequence that has a best local similarity score of 99.9 % between nucleotide 8 and nucleotide 1677 of SEQ ID NO: 1 and encodes at least 15 successive nucleotides of a polynucleotide which is at least 70% identical to a polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2.

Also discussed above, Park et al. teach the *Corynebacterium glutamicum* homoserine O-acetyltransferase gene which comprises a polynucleotide sequence that has a best local similarity score of 99.5 % between nucleotide 1285 and nucleotide 1720 of SEQ ID NO: 1 and encodes at least15 successive nucleotides of a polynucleotide which is at least 70% identical to a polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2. Park et al.

One of ordinary skill in the art at the time of filing would have been motivated to express either of the polynucleotides taught by Hwang et al. or Park et al. in a *coryneform* bacterium so that the encoded proteins could be produced, in order to study the mechanism of actions of each of the identified enzymes involved in methionine biosynthesis in *Corynebacterium glutamicum*. The reasonable expectation of success comes from the high degree of knowledge in the art of heterlogous in vitro protein expression.

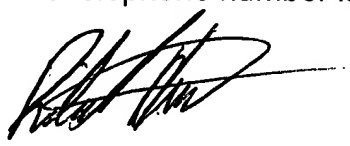
***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
July 10, 2003